

REMARKS

Claims 1-8, 22, 23, 25, 61-63, and 65-75 are currently pending in this application. Claims 9-21, 24, 26-60 and 64 were previously canceled without prejudice or disclaimer. Applicant respectfully reserves the right to prosecute the subject matter of the canceled claims in one or more continuation or divisional applications.

Applicant also respectfully notes that the previous response submitted on May 26, 2005, inadvertently misquoted the M.P.E.P. Specifically, the quoted language in response to the claim rejections under 35 U.S.C. § 103 stated in pertinent part “knowledge generally available to one skilled in the art.” However, the exact language in the M.P.E.P. corresponding to this quote recites “knowledge generally available to one of ordinary skill in the art.” See M.P.E.P. § 2142.

Rejections

Rejections under 35 U.S.C. § 103

A. Claims 1-8, 22, 61-63 and 65-70 were rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Panis *et al*, in view of Fretz *et al*, European Patent No. 0147236, Cino *et al* (U.S. Patent No. 5,527,702) and newly cited Goodrich Jr., *et al* (U.S. Patent No. 5,800,978). According to the Office Action, the claims were deemed *prima facie* obvious.

Applicant respectfully notes that the Office Action acknowledges that Panis *et al* do not disclose incubation techniques in a medium containing cryoprotectant and stabilizer or the use of *Taxus brevifolia* plant cells. However, the Office Action asserts that Fretz *et al* teach incubation after thawing for regeneration of plant cells, and teach plating the thawed plant cells. Furthermore, the Office Action states that European Patent No. 0147236 teaches regeneration of plant cells in a medium containing a stabilizer, such as silver nitrate and other well known inhibitors, and carbon sources such as sugars, and that Cino *et al* teach a medium and culture therefore, of *Taxus brevifolia* cells. The Office Action further states that newly cited Goodrich Jr., *et al*, teach washing the cells after thawing. According to the Office Action, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a method for the recovery of cryopreserved plant cells as disclosed by Panis *et al*, using

the washing technique of newly cited Goodrich, Jr. *et al* and techniques of Fretz *et al* on a regeneration medium containing a stabilizer as disclosed by the EP Patent and further to select for *Taxus* plant cells as disclosed by Cino *et al*.

Applicant respectfully disagrees and traverses this rejection.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met.

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991), MPEP §§ 2142, 2143.

The cryopreservation recovery method of independent claim 1, and each of the claims depending therefrom, requires at least each of the elements of obtaining cryopreserved plant cells, thawing the cryopreserved plant cells by heating the cells to a temperature above which the plant cells are not frozen to obtain thawed plant cells, serially washing the thawed plant cells in media having successively reduced concentrations of at least one cryoprotective agent, said media also containing a stabilizer, and removing the cryoprotective agent and recovering the thawed plant cells.

Applicant submits that there is no motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the teachings of newly cited Goodrich, Jr. *et al*, or to combine the teachings of newly cited Goodrich, Jr. *et al* with the previously cited references, in order to reach the claimed invention. According to the abstract of Goodrich, Jr. *et al*, this reference is generally directed to a process for freezing, including freeze-drying of cells, cell-membranes or cell-like materials using a cryoprotectant medium which stabilizes the cells or membranes for freezing or freeze-drying and allows for freezing or freeze-drying to be performed at -60°C or higher.

However, Applicant submits that the teachings of Goodrich, Jr. *et al* appear directed to the cryopreservation of animal or human cells, and more particularly to specialized types of animal or human cells. For example, in column 4, lines 27-31, Goodrich, Jr. *et al* state that "[t]he present invention provides a method, and cryoprotective compositions for use therewith,

for freezing, including freeze-drying, cells or cell-like materials. The cells and cell-like materials include erythrocytes, platelets, cell-membranes, stem cells, lymphocytes, and the like.” Similarly, Goodrich, Jr. *et al* state that “[t]he cells, cell-membranes and cell-like materials which may be treated according to the present invention include mammalian cells (including human), tissues, peripheral blood cells (red blood cells, platelets, stem cells, leucocytes), mammalian cell membranes, including membranes of periferal [sic] blood cells.” See Goodrich, Jr. *et al*, column 10, lines 38-43. Likewise, the majority of the examples presented in Goodrich, Jr. *et al* are directed to evaluating the effects of varying cryopreservation compositions and conditions on human red blood cells and platelets. See Goodrich, Jr. *et al*, Examples 3-10.

As Goodrich, Jr. *et al* appears to be directed to techniques and compositions for the cryopreservation of animal and human cells, Applicant submits that one of ordinary skill in the art is not motivated by Goodrich, Jr. *et al* or the knowledge generally available to one of ordinary skill in the art, to modify the teachings of Goodrich, Jr. *et al* or to combine the teachings of Goodrich, Jr. *et al* with the previously cited references, in order to reach the claimed invention. As is well known in the biological sciences, plant cells are differentiated from animal cells in part through the existence of a cell wall in plant cells. Due to the presence of a cell wall, one of ordinary skill in the art might reasonably expect cryopreservation techniques specific to animal cells to perform differently when applied to plant cells, and therefore the person of ordinary skill would not rely on the teachings regarding the cryopreservation of animal cells (such as, for example, Goodrich, Jr. *et al*) for techniques adapted for use in the cryopreservation of plant cells.

This is further supported by the Declaration of Michael E. Horn, Ph.D., under 37 C.F.R. §1.132 submitted herewith as the Attachment, wherein it is stated that

[w]hile cryopreservation of animal cultured cells is routine, cryopreservation of cultured plant cells has proven more difficult (See, the instant application, page 7, lines 24-26). Based on my experience, a person of ordinary skill in the art of plant cell culture would not view methods exemplified on human blood cells to be *per se* adaptable to plant cells with any reasonable expectation of success. Results from cryopreservation methods of animal cells are just not predicative of results obtained with plant cells.

See Horn Declaration, paragraph 10. As further stated in the Declaration, “it is unreasonable to suppose that any method that was designed for use using red blood cells, which do not have a cell wall, would be useful using plant cells or vice versa.” See Horn Declaration, paragraph 11.

Accordingly, Applicant submits that one of ordinary skill in the art is not motivated by Goodrich, Jr. *et al* or the knowledge generally available to one of ordinary skill in the art, to modify the teachings of Goodrich, Jr. *et al* or to combine the teachings of Goodrich, Jr. *et al* with the previously cited references directed to plant cells, in order to reach the claimed invention.

Furthermore, the Federal Circuit has stated that

[s]ection 103 precludes...hindsight discounting of the value of new combinations by requiring assessment of the invention as a whole. This court has provided further assurance of an 'as a whole' assessment of the invention under § 103 by requiring a showing that an artisan of ordinary skill in the art at the time of the invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would select the various elements from the prior art and combine them in the claimed manner. In other words, the examiner or court must show some suggestion or motivation, before the invention itself, to make the new combination.

Ruiz v. A.B. Chance Co., 357 F.3D 1270, 1275, 69 U.S.P.Q.2D 1686, 1690 (Fed. Cir. 2004)

Accordingly, Applicant submits that the claims are not obvious over Panis *et al*, in view of Fretz *et al*, European Patent No. 0147236, Cino *et al* (U.S. Patent No. 5,527,702) and newly cited Goodrich Jr., *et al* (U.S. Patent No. 5,800,978). Therefore, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1-8, 22, 61-63 and 65-70 under 35 U.S.C. § 103(a).

B. Claims 23, 25 and 71-75 were rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Panis *et al*, in view of Fretz *et al*, European Patent No. 0147236 and newly cited Goodrich, Jr. *et al* (U.S. Patent No. 5,800,978).

According to the Office Action, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for a method of recovering cryopreserved plant cells as disclosed by Panis *et al* using different cryoprotective agents and an additional step of washing thawed plant cells, as disclosed by Goodrich, Jr. *et al*, with the agents in a medium containing at least one silver salt, such as silver nitrate and other well known inhibitors in the art, and divalent cations as disclosed by Fretz *et al* and EP Patent 0147236, as well as plating the thawed plant cells, also disclosed by Fretz *et al*.

Applicant respectfully disagrees and traverses this rejection.

Applicant respectfully submits that, for the same reasons set forth *supra* in section "A", claims 23, 25 and 71-75 are not rendered unpatentable over Panis *et al*, in view of Fretz *et al*, European Patent No. 0147236 and Goodrich *et al* (U.S. Patent No. 5,800,978), either alone or in combination. Specifically, Applicant submits that there is no motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the teachings of newly cited Goodrich, Jr. *et al* or to combine the teachings of newly cited Goodrich, Jr. *et al* with the previously cited references, in order to reach the claimed invention.

Accordingly, Applicant submits that the claims are not obvious over Panis *et al*, in view of Fretz *et al*, European Patent No. 0147236 and newly cited Goodrich Jr., *et al* (U.S. Patent No. 5,800,978). Therefore, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 23, 25 and 71-75 under 35 U.S.C. § 103(a).

Double Patenting

The Office Action rejected claims 1-8, 22, 23, 25, 61-63 and 65-75 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-48 of U.S. Patent No. 6,753,182 (Kadkade *et al*).

Applicant submits herewith (in duplicate) a terminal disclaimer in compliance with the provisions of 37 C.F.R. § 1.321(c) in response to this obviousness-type double patenting rejection. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 1-8, 22, 23, 25, 61-63 and 65-75 under the judicially created doctrine of obviousness-type double patenting.

Applicant also respectfully notes that an assignment in U.S. Patent application number 08/659,997, conveying the full and exclusive right in and to the invention disclosed in U.S. Patent application number 08/659,997, and in and to any Letters Patent of the United States, including continuations and divisionals, was electronically filed with the USPTO in the instant application on January 11, 2006. The instant application is a Continuation of U.S. Patent application no. 09/307,787, filed May 10, 1999, which is a Divisional of U.S. Patent application no. 08/659,997, filed June 07, 1996. Applicant also electronically filed with the USPTO on the same day two documents evidencing corporate changes of name of the original name of the Assignee. One of the documents evidences the change of name from "Phyton, Inc.", to "Phyton

Biotech, Inc.”, while the other document evidences the change of name from “Phyton Biotech, Inc.”, to “Phyton Holdings, Inc.”

CONCLUSION

An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested.

Respectfully submitted,

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Attachment